DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: PROVENTIL® HFA
Docket No. 96E-0466

JAN 13 1997

#16

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
U.S. Patent and Trademark Office
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 5.439,670 filed by Riker Laboratories, Inc. under 35 U.S.C. § 156. The human drug product claimed by the patent is PROVENTIL® HFA (albuterol sulfate), which was assigned New Drug Application (NDA) No. 20-503.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records indicate that it **does not** represent the first permitted commercial marketing or use of the product. For example, Ventolin, Volmax, Combivent, and Albuterol Sulfate have been approved by various manufacturers and contain the same active ingredient in PROVENTIL® HFA, albuterol sulfate.

The NDA was approved on August 15, 1996, which makes the submission of the patent term extension application on October 11, 1996, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Ted K. Ringsred
3M/Office of Intellectual Property Counsel
P.O. Box 33427 / St. Paul, MN 55133-3427